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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,471	10/28/2003	Janaswamy Madhusudana Rao	0640/71348/JPW/AG	5608
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John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER 1655
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/695,471	Applicant(s) RAO ET AL.
	Examiner Michele Flood	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 June 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,6,7 and 9-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/136/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-4 and 6-12, as well as the species election of *Cyclea peltata* in the reply filed on June 23, 2008 is acknowledged. The traversal is on the ground that it would not be an undue burden for the Examiner to search both inventions. This is not found persuasive for all of the reasons set forth clearly in the requirement for restriction and election of species mail dated March 19, 2008. Moreover, contrary to Applicant's argument, a search for prior art with regard to any of Groups I-II would not necessarily identify art for the other group. For instance, the invention of Group II requires each of the claim-designated ingredients recited in the Markush of Group I, whereas the invention of Group I only requires the presence of only 5 of the claim-designated recited therein the Markush group. As such, additional search terms, electronic resources and search queries would be required. Applicant is reminded of the extensive literature search in biotechnology. Thus, the search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on the elected species, namely *Cyclea peltata* readable on Claims 1, 2, 4, 6, 7 and 9-12.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 6, 7 and 9-12 are under examination.

Claim Rejections - 35 USC § 112

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where Applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "resin" in Claim 12 is used by the claim to mean "plant part", while the accepted meaning is "a semisolid substance secreted in the sap of some plants and trees." The term is indefinite because the specification does not clearly redefine the term. Thus, while it is known in the art that resin is a phytochemical obtained from a plant part of *Ferula asafetida*, resin of *Ferula asafetida* is not a plant part.

Given the foregoing as set forth immediately, the metes and bound of Claim 12 are rendered vague and indefinite by the phrase, "wherein the plant part of *Ferula asafetida* is a resin", because it is unclear as to the subject matter to which Applicant

intends to seek protection. The lack of clarity renders the claim confusing and ambiguous.

Claim Rejections - 35 USC § 103

Claims 1, 2, 6, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palpu (A*), Hong-Yue (B*), Dehpour (U), Yoshida et al. (N), Lewis et al. (V) and Rao et al. (W).

Applicant claims a herbal composition for the treatment of gastric ulcer, the composition comprising powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsinoides* and, one or more pharmaceutically acceptable additives or carriers, wherein the composition comprises each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportions has a value greater than zero. Applicant further claims the composition as claimed in claim 1, wherein the composition comprises powdered plant parts of each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum* in equal proportions by weight, and one or more pharmaceutically acceptable additives or carriers. Applicant further claims the composition as claimed in claim 1, wherein the plant part of each of *Trachyspermum roxburghianum*, *Embelia ribes* and *Coriandum sativum* is a fruit; wherein the plant part

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of *Cyclea peltata* and *Glycyrrhiza glabra* is a root; wherein the plant of *Asparagus racemosus* is a tuber; wherein the plant part of *Sesamum indicum* is a seed; and, wherein the plant of *Musa sapientum* is an unripe fruit.

Firstly, Palpu beneficially teaches a herbal composition for the treatment of gastric ulcer comprising powdered tuber of *Asparagus racemosus* and other powdered plant parts of other plants (read herein as a pharmaceutically acceptable additive or carrier). See patent claims.

Secondly, Hong-Yue beneficially teaches an antipeptic ulcer comprising powdered liquorice and clove (read herein as a pharmaceutically acceptable additive or carrier.); and, Dehpour teaches a composition comprising root powder of *Glycyrrhiza glabra* that is used to coat ibuprofen (read herein as a pharmaceutically acceptable additive or carrier), which is used to treat gastric lesions.

Thirdly, Yoshida beneficially teaches a composition comprising a powdered seed oil extract of *Sesamum indicum* that is beneficial in the treatment for peptic ulcers.

Fourthly, Lewis beneficially teaches a composition comprising unripe fruit powder of *Musa sapientum* and food (read herein as a pharmaceutically acceptable additive or carrier) having anti-ulcerogenic properties, on page 285, Column 1, under "2.6. Acid stability".

Finally, Rao teaches a herbal composition for the treatment of gastric ulcer comprising fruit powder of *Carum roxburghianum* (also known in the art of botany as *Trachyspermum roxburghianum*), on page 16, Column 2, under "Powder".

The individual teachings of Palpu, Hong-Yue, Dehpour, Yoshida, Lewis and Rao are set forth above. Neither Palpu, Hong-Yue, Dehpour, Yoshida, Lewis nor Rao teaches a composition comprising each of the claim-designated ingredients. However, each of the individual teachings of Palpu, Hong-Yue, Dehpour, Yoshida, Lewis and Rao does teach that each of the claim-designated powdered plant parts are useful for treating gastric ulcers. Thus, it was known in the art at the time of the invention that powdered plants of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* are useful in treating gastric ulcers. Therefore, an artisan of ordinary skill in the art would have had a reasonable expectation that using the claim-designated powdered plant parts, as taught by the aforementioned cited references, to formulate a herbal composition to treat gastric ulcer would be successful. This reasonable expectation of success would have motivated one of ordinary skill in the art to combine the ingredients taught by the prior art references to provide the instantly claimed invention. Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Given the combined teachings as a whole, at the time the invention was made, one of ordinary skill in the art would have been motivated, and one would

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have had a reasonable expectation of success to combine the powdered plant parts taught by Palpu, Hong-Yue, Dehpour, Yoshida, Lewis and Rao to provide the instantly claimed invention because the prior art references taught that powdered plants of the claim-designated exert the beneficial functional effect of anti-ulcer activity.

While the combined teachings of the references do not specifically teach combining the ingredients in the amounts claimed by Applicant, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955). The references recognize that the amounts of the claim-designated ingredients can be modified. Therefore, it would have been customary for an artisan of ordinary skill to determine the optimal amount of each of the ingredients to add in order to best achieve the desired results. Thus, absent some clear demonstration of unexpected results from the claimed parameters, this optimization of ingredient amounts would have been obvious at the time the instantly claimed invention was made. Applicant's invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him or her.

Claims 1, 2, 4, 6, 7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palpu (A*), Hong-Yue (B*), Dehpour (U), Yoshida et al. (N), Lewis et al. (V) and Rao et al. (W) in view of Purohit et al. (X), Yang (O), Khrenova et al. (U1), Warrier (P.K. Warrier, Indian Medicinal Plants - A compendium of 500 species (1994-1996); Vol. 2, pg. 277-278, published by Orient Longman, Chennai) and McAnalley (C*).

Applicant's claimed invention of Claims 1, 2, 6, 7 and 9-11 was set forth above. Applicant further claims the composition as claimed in claim 1, wherein the composition comprises powdered plant parts of each of *Asparagus racemosus*, *Glycyrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum*, *Evolvulus alsinoides*, *Ferula asafetida*, *Coriandrum sativum*, *Cyclea peltata* and *Aloe barbadensis* in equal proportions by weight, and one or more pharmaceutically acceptable additives or carriers. Applicant further claims the composition as claimed in claim 1, wherein the plant part of *Ferula asafetida* is a resin.

The combined teachings of Palpu, Hong-Yue, Dehpour, Yoshida, Lewis and Rao are set forth immediately above. The combined teachings teach the instantly claimed herbal composition for the treatment of gastric ulcer except for *Evolvulus alsinoides*, *Ferula asafetida*, *Coriandrum sativum*, *Cyclea peltata* and *Aloe barbadensis* in equal

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proportions by weight. However, it would have been obvious to one of ordinary skill in the art to add the claim-designated ingredients to the composition taught by the combined teachings of Palpu, Hong-Yue, Dehpour, Yoshida, Lewis and Rao to provide the instantly claimed herbal composition because at the time the invention was made each of the ingredients were known in the art as being beneficial in the making of a composition to treat gastric ulcer made evident by the teachings of Purohit, Yang, Khrenova, *Cyclea peltata*, McAnalley, respectively. Firstly, Purohit teaches a herbal composition for the treatment of gastric ulcer comprising an alcohol extract of fruit powder of *Evolvulus alsinoides*. Secondly, Yang teaches a herbal composition for the treatment of gastric ulcer comprising asafetida (also known in the art of botany as *Ferula asafetida*). Thirdly, Khrenova teaches a herbal composition for the treatment of gastric ulcer comprising a fruit extract of *Coriandrum sativum*. Fourthly, on page 277, Warrier teaches that the roots of *Cyclea peltata* are traditionally used for the treatment of dyspepsia and ulcers. Finally, McAnalley teaches a composition for the treatment of gastric ulcer comprising powdered *Aloe vera* (also known in the art of botany as *Aloe barbadensis*), in Column 29, lines 35-43. In Column 30, lines 34-67, McAnalley teaches a powdered *Aloe vera* in a phosphate buffer (read herein as a pharmaceutically acceptable additive or carrier).

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same

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purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
September 21, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655